

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
24 February 2005 (24.02.2005)

PCT

(10) International Publication Number
WO 2005/016447 A2

(51) International Patent Classification⁷: A61N 1/05

(21) International Application Number:
PCT/US2004/024552

(22) International Filing Date: 28 July 2004 (28.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/637,342 8 August 2003 (08.08.2003) US

(71) Applicant (for all designated States except US): AD-
VANCED NEUROMODULATION SYSTEMS, INC.
[US/US]; 6901 Preston Rd., Plano, TX 75024 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): DAGLOW, Terry
[US/US]; 1005 Ashland Court, Allen, TX 75013 (US).

(74) Agent: KENNERLY, Christopher, W.; Baker Botts, LLP,
2001 Ross Avenue, Dallas, TX 75201 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,

GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,
SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii)) for all designations
- as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii)) for the following desig-
nation US

Published:

- without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHOD FOR IMPLANTING AN ELECTRICAL STIMULATION SYSTEM AND A PADDLE
STYLE ELECTRICAL STIMULATION LEAD

(57) Abstract: In one embodiment, an introducer is provided for implanting an electrical stimulation lead to enable electrical stimu-
lation of nerve tissue. The introducer includes an outer sheath and an inner penetrator. The outer sheath is configured to accommodate
insertion of the electrical stimulation lead through the outer sheath and may be inserted into a human body near the nerve tissue. The
inner penetrator is removably housed within the outer sheath and includes an inner channel configured to accommodate a guide wire.
The inner penetrator may be advanced along the guide wire to a desired location relative to the nerve tissue and removed from the
outer sheath leaving the outer sheath substantially in position for insertion of the electrical stimulation lead through the outer sheath
into position proximate the nerve tissue.



WO 2005/016447 A2

APPARATUS AND METHOD FOR IMPLANTING AN ELECTRICAL STIMULATION SYSTEM AND A PADDLE STYLE ELECTRICAL STIMULATION LEAD

TECHNICAL FIELD OF THE INVENTION

This invention relates generally to electrical stimulation leads for medical applications and in particular to an apparatus and method for implanting an electrical stimulation system that includes a paddle style electrical stimulation lead.

5

BACKGROUND

Electrical energy is applied to the spinal cord and peripheral nerves to treat regions of the body that are affected by chronic pain from a variety of etiologies. One method of delivering electrical energy is to implant an electrode and position it in a precise location adjacent the spinal cord such that stimulation of the electrode causes a subjective sensation of numbness or tingling in the affected region of the body, known as "paresthesia." Pain managing electrical energy is commonly delivered through electrodes positioned external to the dura layer surrounding the spinal cord. The electrodes may be carried by either of two primary vehicles: a percutaneous lead and a laminotomy or "paddle" lead.

Percutaneous leads commonly have three or more equally-spaced electrodes. They are positioned above the dura layer using a needle that is passed through the skin, between the desired vertebrae and onto the top of the dura. Percutaneous leads deliver energy radially in all directions because of the circumferential nature of the electrode. Percutaneous leads can be implanted using a minimally invasive technique. In a typical percutaneous lead placement, a trial stimulation procedure is performed to determine the optimal location for the lead. Here, a needle is placed through the skin and between the desired vertebrae. The percutaneous lead is then threaded through the needle into the desired location over the spinal cord dura. Percutaneous leads may also be positioned in other regions of the body near peripheral nerves for the same purpose.

Laminotomy or paddle style leads have a paddle-like configuration and typically possess multiple electrodes arranged in one or more independent columns. Paddle style leads provide a more focused energy delivery than percutaneous leads because electrodes may be present on only one surface of the lead. Paddle style leads may be desirable in certain

situations because they provide more direct stimulation to a specific surface and require less energy to produce a desired effect. Because paddle style leads are larger than percutaneous leads, they have historically required surgical implantation through a procedure known as partial laminectomy that requires the resection and removal of vertebral tissue.

5

SUMMARY OF THE INVENTION

The present invention provides an introducer and process for implanting a paddle style electrical stimulation lead.

In one embodiment, an introducer is provided for implanting an electrical stimulation
10 lead to enable electrical stimulation of nerve tissue. The introducer includes an outer sheath and an inner penetrator. The outer sheath is configured to accommodate insertion of the electrical stimulation lead through the outer sheath and may be inserted into a human body near the nerve tissue. The inner penetrator is removably housed within the outer sheath and includes an inner channel configured to accommodate a guide wire. The inner penetrator
15 may be advanced along the guide wire to a desired location relative to the nerve tissue and removed from the outer sheath leaving the outer sheath substantially in position for insertion of the electrical stimulation lead through the outer sheath into position proximate the nerve tissue.

In another embodiment, a method is provided for implanting an electrical stimulation
20 lead to enable electrical stimulation of nerve tissue. The method includes inserting a needle into tissue, removing the needle, forming a tract for the electrical stimulation lead by spreading tissue using an introducer including an outer sheath and an inner penetrator removably housed within the outer sheath, removing the inner penetrator, leaving the outer sheath substantially in position, and inserting the electrical stimulation lead through the outer
25 sheath until the electrical stimulation lead is positioned proximate the nerve tissue.

In another embodiment, a method is provided for implanting an electrical stimulation lead in a minimally invasive percutaneous manner to enable electrical stimulation of a human's spinal nerve tissue. The method includes inserting a needle into the human's epidural space and inserting a guide wire through the needle until an end of the guide wire is
30 positioned in the epidural space at a desired location relative to the spinal nerve tissue to be stimulated. The position of the guide wire in the epidural space is verified using fluoroscopy. The needle is then removed, leaving the guide wire substantially in position. An introducer including an outer sheath and an inner penetrator, the inner penetrator removably housed

within the outer sheath and including an inner channel configured to accommodate the guide wire, is then advanced along the guide wire until an end of the inner penetrator of the introducer is positioned in the epidural space at a desired location with respect to the spinal nerve tissue to be stimulated, the outer sheath of the introducer forming a tract as the inner penetrator of the introducer advances along the guide wire. The outer sheath of the introducer has a width of at least approximately two times its height. The position of the introducer in the epidural space is verified using fluoroscopy. The guide wire and the inner penetrator of the introducer are then removed, leaving the outer sheath of the introducer substantially in position. The paddle style electrical stimulation lead is then inserted through the outer sheath of the introducer until the paddle style electrical stimulation lead is positioned in the epidural space proximate the nerve tissue to be stimulated. The position of the paddle style electrical stimulation lead in the epidural space is verified using fluoroscopy.

In another embodiment, a method of implanting a system to enable electrical stimulation of a human's nerve tissue is provided. The method includes inserting a needle into tissue proximate the nerve tissue to be stimulated. A guide wire is inserted through the needle until an end of the guide wire is positioned at a desired location relative to nerve tissue to be stimulated. The needle is then removed leaving the guide wire substantially in position. An introducer including an outer sheath and an inner penetrator, the inner penetrator removably housed within the outer sheath and including an inner channel configured to accommodate the guide wire, is then advanced along the guide wire until an end of the inner penetrator of the introducer is positioned at a desired location relative to the peripheral nerve tissue to be stimulated, the outer sheath of the introducer forming an insertion tract as the inner penetrator of the introducer advances along the guide wire. The guide wire and the inner penetrator of the introducer are then removed, leaving the outer sheath of the introducer substantially in position. An electrical stimulation lead is then inserted through the outer sheath of the introducer until the electrical stimulation lead is positioned proximate the peripheral nerve tissue to be stimulated. The outer sheath is removed. The electrical stimulation lead is connected to a generator. A subcutaneous pocket is created for the generator and the generator is inserted into it.

In another embodiment, a system for implanting an electrical stimulation lead to enable electrical stimulation of a human's spinal nerve tissue is provided. The introducer includes an outer sheath and an inner penetrator. The outer sheath is configured to accommodate insertion of the electrical stimulation lead through the outer sheath and may be

inserted through the human's skin and into the human's epidural space. The inner penetrator is removably housed within the outer sheath and includes an inner channel configured to accommodate a guide wire. The inner penetrator may be advanced along the guide wire until an end of the inner penetrator is positioned in the epidural space at a desired location relative to spinal nerve tissue to be stimulated, the outer sheath forming an insertion tract as the inner penetrator advances along the guide wire. The inner penetrator is configured to be removed from the outer sheath leaving the outer sheath substantially in position for insertion of the electrical stimulation lead through the outer sheath into position proximate the spinal nerve tissue to be stimulated. The system also includes an implantable generator to power the electrical stimulation lead.

In another embodiment, a needle for introduction of a paddle style electrical stimulation lead near a spinal column of a human includes in combination a body having a proximal end and a distal end, a lumen having a continuous oblong cross section defined by a solid outer wall, and a stylet having a handle at a proximal end and a solid body extending from the proximal end to a distal end and adapted to be inserted within the lumen, the improvement comprising a raised circumferential ridge configured to create resistance when the circumferential ridge contacts the human's ligamentum flavum.

Particular embodiments of the present invention may provide one or more technical advantages. For example, certain embodiments may allow a paddle style electrical stimulation lead to be inserted using a minimally invasive procedure, using an introducer, rather than a partial laminectomy or other more invasive surgical procedure. Certain embodiments may provide a guide wire, introducer and paddle style electrical stimulation lead composed in part or entirely of radio-opaque material to allow for fluoroscopic verification of the position of the guide wire, introducer and lead. Certain embodiments may provide an inner penetrator including a hollow tip configured to extend beyond the outer sheath, the tip having a raised circumferential ridge configured to create resistance when the circumferential ridge contacts the human's tissue. Certain embodiments may provide all, some, or none of these advantages. Certain embodiments may provide one or more other technical advantages, one or more of which may be readily apparent to those skilled in the art from the figures, description and claims included herein.

BRIEF DESCRIPTION OF THE DRAWINGS

To provide a more complete understanding of the present invention and the features and advantages thereof, reference is made to the following description taken in conjunction with the accompanying drawings, in which:

5 FIGURE 1A illustrates an example introducer for implanting a paddle style electrical stimulation lead;

FIGURE 1B illustrates an example inner penetrator of an introducer for implanting a paddle style electrical stimulation lead;

10 FIGURE 1C illustrates an example of an outer sheath of an introducer for implanting a paddle style electrical stimulation lead;

FIGURE 1D illustrates an example of a tip of an introducer for implanting a paddle style electrical stimulation lead;

FIGURE 1E illustrates an example of a tip of an outer sheath of an introducer for implanting a paddle style electrical stimulation lead;

15 FIGURE 1F illustrates a side view of an example of a tip of an introducer for implanting a paddle style electrical stimulation lead;

FIGURE 2A illustrates an example of a needle inserted into a human's epidural space;

FIGURE 2B illustrates an example of a guide wire being inserted through a needle into a human's epidural space;

20 FIGURE 2C illustrates an example of an introducer being inserted over a guide wire into a human's epidural space;

FIGURE 2D illustrates an example of an inner penetrator being removed from the outer sheath of an introducer in a human's epidural space;

25 FIGURE 2E illustrates an example of a paddle style lead being inserted through an introducer into a human's epidural space;

FIGURE 2F illustrates an example of a paddle style lead implanted in a human's epidural space;

FIGURE 3A illustrates an example of a stimulation system;

FIGURE 3B illustrates an example of a stimulation system; and

30 FIGURE 4 is a flow chart describing steps for implanting a stimulation system.

DESCRIPTION OF EXAMPLE EMBODIMENTS

FIGURE 1A illustrates an example introducer 10 for implanting a paddle style electrical stimulation lead percutaneously. Introducer 10 may be used to percutaneously introduce a percutaneous or paddle style lead into the epidural space of a user who requires electrical stimulation treatment directed to spinal nerve tissue, for example, for pain management. As known in the art, paddle style leads generally have a width about two times the height of the face of the paddle. The same or an analogous, perhaps smaller, introducer 10 may be used to implant a percutaneous or paddle style lead into other tissue for electrostimulation treatment of a peripheral nerve. In one embodiment, introducer 10 includes an outer sheath 12 and an inner penetrator 14.

FIGURE 1B illustrates an example inner penetrator 14 disassembled from outer sheath 12. Inner penetrator 14 includes handle 16, connector 17, and body 18 having proximal end 19 and distal end or tip 20. Tip 20 may be tapered. Connector 17 connects handle 16 to body 18. An inner channel 22 is formed through handle 16 and body 18 and connects opening 26 of handle 16 to opening 21 of tip 20. Inner channel 22 may be configured to attach to a syringe. Inner channel 22 is wide enough to accommodate guide wires of various sizes along which introducer 10 may be advanced during use. Channel 22 may taper or otherwise decrease in diameter as it traverses connector 17 at the handle-body junction. Inner penetrator 14 may be formed from a plastic, such as silastic or another polymer, or any other suitable material. Tip 20 of inner penetrator 14 may be curved as shown in FIGURES 1A-C or may be curved into any other suitable shapes by an operator before inserting the introducer. In certain embodiments, inner penetrator 14 may be bent or curved into a suitable configuration to allow passage around an anatomical obstruction, or formed into any other shape suitable for particular anatomic regions of the body.

FIGURE 1C illustrates outer sheath 12 disassembled from inner penetrator 14. The lumen of outer sheath 12 may range in width, for example from approximately 2mm to approximately 6mm. The lumen may be oblong, oval, or substantially rectangular as needed to accommodate paddle style leads of various configurations. Outer sheath 12 may taper slightly at tip 29. Tip 29 of outer sheath 12 may be beveled to allow easier passage through tissue and to allow inner penetrator 14 to protrude out of tip 29.

Outer sheath 12 is preferably formed from a metal, such as stainless steel or titanium, or any other suitable material that is stiff and resists bending when outer sheath 12 is inserted through the paravertebral tissue and into the epidural space. In one embodiment, inner

penetrator 14 includes tapered tip 20 shown in FIGURE 1D. Tapered tip 20 protrudes out of outer sheath 12. Tapered tip 20 preferably allows introducer 10 to pass easily over a guide wire without creating a false passage in an undesirable location in the tissue.

In one embodiment of outer sheath 12, shown in FIGURES 1D-F, tip 20 includes a raised circumferential shoulder or ridge 23 configured to provide an indication or "feel" to a physician as raised ridge 23 comes in contact with the ligamentum flavum. This "feel" occurs when raised ridge 23 comes in contact with the ligamentum flavum causing a slight resistance, pressure, or "notch" feel to the physician as raised ridge 23 comes in contact with and passes through the ligamentum flavum. As many physicians rely on "feel" while performing delicate procedures, this aspect may provide an important indication to the physician as to the location of outer sheath 12 and thus introducer 10 as a whole.

Such a raised ridge 23 can also be applied to needles or cutting devices that otherwise fail to provide physicians sufficient "feel" or a locative indication as the needle cuts through the ligamentum flavum. For example, the edge of outer sheath 12 in FIGURE 1E could be configured into a cutting surface for a paddle insertion type needle. The improvement of raised ridge 23 on such a cutting device would provide the needed "feel" or indication to the physician as to where the needle was in the human tissue, thus providing confidence to the physician, as the physician uses such a large needle, that the needle has not yet entered the interthecal space.

Further, raised ridge 23 assists in spreading the fibers of the paravertebral muscle and ligaments as it is inserted. Raised ridge 23 may be angled to assist insertion, for example, at an angle of thirty-five to forty-five degrees or any other angle that would facilitate passage of outer sheath through tissue. During insertion, raised ridge 23 ultimately makes contact with the ligamentum flavum and rests against it during insertion of a guide wire and an electrical stimulation lead.

In one embodiment, outer sheath 12, inner penetrator 14, or both may be formed from radio-opaque material or may include radio-opaque markers that allow the position of outer sheath 12, inner penetrator 14, or both to be visualized with fluoroscopy or plain x-rays, for example, during the insertion process to insure proper positioning in the epidural space.

FIGURES 2A-F illustrate an example method of implanting a paddle style electrical stimulation lead into a human's epidural space using an example introducer 10. Spinal cord 47 is also shown. A location between two vertebrae is selected for the procedure. The site may be selected using fluoroscopy. The first step in performing the procedure is to insert

needle 41, preferably at an angle, into the skin, and through the subcutaneous tissue and ligamentum flavum 44 of the spine, and into a human's epidural space 40. In one embodiment of the method, for example, the introducer might be inserted at an angle of approximately thirty-five to approximately forty-five degrees. FIGURE 2A illustrates
5 insertion of needle 41 through the skin between spinous processes 42 of two vertebrae 43. Entry into epidural space 40 by needle 41 may be confirmed using standard methods such as the "loss-of-resistance" technique after stylet 45, or inner portion of needle 41, is removed.

After removing stylet 45 from needle 41, guide wire 46 may be inserted through needle 41 into epidural space 40, shown in FIGURE 2B. A guide wire is used in a preferred
10 embodiment of the method of insertion but is not required to insert a paddle style lead through the introducer. This part of the procedure may be performed under fluoroscopic guidance for example. Fluoroscopy may be used to check the position of guide wire 46 in epidural space 40 before inserting introducer 10. Once the tip of guide wire 46 is within epidural space 40, needle 41 is removed. As shown in FIGURE 2C, introducer 10 may then
15 be inserted, preferably at an angle of approximately thirty-five to approximately forty-five degrees, although the exact angle may differ depending on technique and a patient's anatomy, over guide wire 46 and into epidural space 40 using guide wire 46 as a guide. The technique of passing introducer 10 over guide wire 46 helps ensure proper placement of introducer 10 into epidural space 40 and helps avoid inadvertent passage of introducer 10 into an unsuitable
20 location. The operator may choose to cut the skin around the insertion site with a scalpel to facilitate subsequent entry of introducer 10 through the needle entry site.

As introducer 10 is passed through the skin it elongates the hole in the skin made by needle 41. As introducer 10 is passed deeper into the paravertebral tissues, it spreads the fibers of tissue, muscle and ligamentum flavum 44 and forms a tract through these tissues and
25 into epidural space 40, preferably without cutting the tissues. At the level in the tissues where introducer 10 meets and penetrates ligamentum flavum 44 there is a second loss of resistance when inner penetrator 14 has completely penetrated the ligamentum flavum 44. Shoulder or ridge 23 of outer sheath 12 is preferably lodged against ligamentum flavum 44 during insertion of a paddle style lead.

30 Once introducer 10 has completely penetrated ligamentum flavum, inner penetrator 14 and guide wire 46 may be removed, leaving outer sheath 12 positioned in epidural space 40, as shown in FIGURE 2D. As shown in FIGURE 2E, paddle style lead 50 may then be inserted through outer sheath 12 and positioned at an optimal vertebral level, using

fluoroscopy for example, for the desired therapeutic effect. As shown in FIGURE 2F, outer sheath 12 may then be removed leaving only paddle style lead 50 in epidural space 40, where paddle style lead 50 can be further manipulated if necessary to achieve a desired therapeutic effect. Paddle style lead 50 may be secured by suturing it to a spinous process.

5 As described above, introducer 10 may be used to implant paddle style lead 50 into epidural space 40 for spinal nerve stimulation. The same or an analogous, perhaps smaller, introducer 10 may be used to implant an analogous paddle style lead 50 into any appropriate region of the body for peripheral nerve stimulation. For example, such a paddle style lead 50 may have an outer sheath 12 and lumen 28 with a width of approximately 1mm to
10 approximately 3mm.

A similar method of insertion (not expressly shown) may be used to implant a paddle style electrical stimulation lead into a human's peripheral nerve tissue. In this embodiment of the invention a site for insertion in tissue near a nerve is selected. The first step in performing the procedure is to insert a needle into the skin and through the subcutaneous
15 tissue and into tissue near a peripheral nerve. If the needle has a stylet, it may be removed and a guide wire may be inserted through the needle and into the tissue near a peripheral nerve. A guide wire may not be required. Fluoroscopy may or may not be used to guide insertion of a guide wire into tissue near a peripheral nerve. Once the tip of the guide wire, or
20 needle, is in the tissue near a peripheral nerve, introducer 10 may be inserted, preferably at an angle that would depend on the anatomy of the body near the peripheral nerve to be stimulated. As introducer 10 is passed through tissues, it elongates the tract made by a needle or guide wire and spreads the tissue. After positioning introducer 10 in tissue adjacent to the peripheral nerve to be stimulated, inner penetrator 14 is removed. A paddle style lead may then be inserted through outer sheath 12. Outer sheath 12 may then be removed leaving only
25 the paddle style lead in position near the peripheral nerve to be stimulated.

Now referring to FIGURES 3A and 3B, there are shown two embodiments of a stimulation system 200, 300 in accordance with the present invention. The stimulation systems generate and apply a stimulus to a tissue or to a certain location of a body. In general terms, the system 200, 300 includes a stimulation or energy source 210, 310 and a lead 50 for
30 application of the stimulus. The lead 110 shown in FIGURES 3A and 3B is the paddle style lead 50 of the present invention.

As shown in FIGURE 3A, the stimulation system 200 includes the lead 50 that is coupled to the stimulation source 210. In one embodiment, the stimulation source 210

includes an implantable pulse generator (IPG). As is known in the art, an implantable pulse generator (IPG) is implanted within the body (not shown) that is to receive electrical stimulation from the stimulation source 210. An example IPG may be one manufactured by Advanced Neuromodulation Systems, Inc., such as the Genesis® System, part numbers 3604, 3608, 3609, and 3644.

As shown in FIGURE 3B, the stimulation system 300 includes the lead 50 that is coupled to the stimulation source 310. The stimulation source 310 includes a wireless receiver. As is known in the art, the stimulation source 310 comprising a wireless receiver is implanted within the body (not shown) that is to receive electrical stimulation from the stimulation source 310. An example wireless receiver 310 may be those wireless receivers manufactured by Advanced Neuromodulation Systems, Inc., such as the Renew® System, part numbers 3408 and 3416.

The wireless receiver (not shown) within stimulation source 310 is capable of receiving wireless signals from a wireless transmitter 320. The wireless signals are represented in FIGURE 3B by wireless link symbol 330. The wireless transmitter 320 and a controller 340 are located outside of the body that is to receive electrical stimulation from the stimulation source 310. A user of the stimulation source 310 may use the controller 340 to provide control signals for the operation of the stimulation source 310. The controller 340 provides control signals to the wireless transmitter 320. The wireless transmitter 320 transmits the control signals (and power) to the receiver in the stimulation source 310 and the stimulation source 310 uses the control signals to vary the signal parameters of the electrical signals that are transmitted through lead 110 to the stimulation site. An example wireless transmitter 320 may be those transmitters manufactured by Advanced Neuromodulation Systems, Inc., such as the Renew® System, part numbers 3508 and 3516.

As will be appreciated, the connectors are not visible in FIGURES 3A and 3B because the contact electrodes are situated within a receptacle (not shown) of the stimulation source 210, 310. The connectors are in electrical contact with a generator (not shown) of electrical signals within the stimulation source 210, 310. The stimulation source 210, 310 generates and sends electrical signals via the lead 50 to the electrodes 160. Understandably, the electrodes 160 are located at a stimulation site (not shown) within the body that is to receive electrical stimulation from the electrical signals. A stimulation site may be, for example, adjacent to one or more nerves in the central nervous system (e.g., spinal cord) or peripheral nerves. The stimulation source 210, 310 is capable of controlling the electrical

signals by varying signal parameters (e.g., intensity, duration, frequency) in response to control signals that are provided to the stimulation source 210, 310.

As described above, once lead 110 is inserted into either the epidural space or near the peripheral nerve, introducer 10 is removed. Lead 110 extends from the insertion site to the implant site (the area of placement of the generator). The implant site is typically a subcutaneous pocket that receives and houses the IPG or receiver (providing stimulation source 210, 310). The implant site is usually positioned a distance away from the stimulation site, such as near the buttocks or other place in the torso area. In most cases, the implant site (and insertion site) is located in the lower back area, and lead 110 may extend through the epidural space (or other space) in the spine to the stimulation site (e.g., middle or upper back, neck, or brain areas). Once the system is implanted, the system of leads and/or extensions may be subject to mechanical forces and movement in response to body movement. FIGURE 4 illustrates the steps that may be used to implant a stimulation system 200, 300 into a human.

Although the present invention has been described with several embodiments, a number of changes, substitutions, variations, alterations, and modifications may be suggested to one skilled in the art, and it is intended that the invention encompass all such changes, substitutions, variations, alterations, and modifications as fall within the spirit and scope of the appended claims.

WHAT IS CLAIMED IS:

1. An introducer for implanting an electrical stimulation lead to enable electrical stimulation of nerve tissue, comprising:

5 an outer sheath to accommodate insertion of the electrical stimulation lead through the outer sheath, the outer sheath operable to be inserted into a human body near the nerve tissue; and

an inner penetrator removably housed within the outer sheath and comprising an inner channel configured to accommodate a guide wire, the inner penetrator configured to be advanced along the guide wire to a desired location relative to the nerve tissue and removed
10 from the outer sheath leaving the outer sheath substantially in position for insertion of the electrical stimulation lead through the outer sheath into position proximate the nerve tissue.

2. The introducer of Claim 1, wherein the lead is greater than 1.5 millimeters in width.

3. The introducer of Claim 1, wherein the electrical stimulation lead has a width
15 of at least approximately two times its height.

4. The introducer of Claim 1, wherein the electrical stimulation lead is a paddle style lead.

5. The introducer of Claim 1, wherein the nerve tissue comprises spinal nerve tissue and the desired location comprises an epidural space of the human.
20

6. The introducer of Claim 1, wherein the nerve tissue comprises a peripheral nerve.

7. The introducer of Claim 1, wherein the inner penetrator comprises a hollow tip
25 configured to extend beyond the outer sheath.

8. The introducer of Claim 1, wherein the outer sheath has a raised circumferential ridge configured to create resistance when the circumferential ridge contacts the human's ligamentum flavum.
30

9. The introducer of Claim 1, wherein the inner penetrator and outer sheath comprise one or more radio-opaque markers for visualization using fluoroscopy.

10. The introducer of Claim 1, wherein the outer sheath has a substantially oval cross-section.

5 11. The introducer of Claim 1, wherein the outer sheath has a substantially oblong cross-section.

12. The introducer of Claim 1, wherein the outer sheath is formed of metal comprising titanium or stainless steel.

10 13. The introducer of Claim 1, wherein the inner penetrator is formed from one or more of plastic, silastic, or a polymeric material.

14. The introducer of Claim 1, wherein the tip of the outer penetrator is tapered.

15. The introducer of Claim 1, wherein the tip of the inner penetrator and the tip of the outer sheath comprise a curved portion to allow passage of the inner penetrator and outer sheath around an anatomical obstruction.

15 16. The introducer of Claim 1, wherein the inner penetrator is configured to be advanced until an end of the inner penetrator is positioned in the human's epidural space at a desired location relative to the nerve tissue such that the outer sheath forms an insertion tract for the electrical stimulation lead as the inner penetrator advances along the guide wire.

20 17. A method of implanting an electrical stimulation lead to enable electrical stimulation of nerve tissue, comprising:

inserting a needle into tissue;

removing the needle;

25 forming a tract for the electrical stimulation lead by spreading tissue using an introducer comprising an outer sheath and inner penetrator removably housed within the outer sheath;

removing the inner penetrator;

leaving the outer sheath substantially in position; and

inserting the electrical stimulation lead through the outer sheath until the electrical stimulation lead is positioned proximate the nerve tissue.

18. The method of Claim 17, further comprising:
positioning the guide wire through the needle into a desired location relative to the
nerve tissue;

5 advancing the introducer along the guide wire; and
positioning the introducer at a desired location.

19. The method of Claim 17, wherein forming the tract further comprises:
advancing the introducer along a channel created by the needle; and
locating a ligamentum flavum with a circumferential ridge on the outer sheath.

20. The method of Claim 17, wherein the electrical stimulation lead comprises a
10 paddle style lead.

21. The method of Claim 18, wherein the nerve tissue comprises spinal nerve
tissue and the electrical stimulation lead is positioned in an epidural space of a human.

22. The method of Claim 17, wherein the nerve tissue comprises a peripheral
nerve.

15 23. The method of Claim 18, further comprising verifying the position of one or
more of the guide wire, introducer, and the electrical stimulation lead using fluoroscopy.

24. The method of Claim 17, wherein the tip of the introducer is tapered and
hollow.

25. The method of Claim 17, wherein the tip of the introducer comprises a curved
20 portion to allow passage of the introducer around an anatomical obstruction.

26. The method of Claim 17, wherein the outer sheath comprises a circumferential
ridge configured to create resistance when the circumferential ridge contacts a ligamentum
flavum of a human.

27. The method of Claim 18, wherein the needle comprises a removable stylet
25 configured to be removed before inserting the guide wire.

28. A method of implanting an electrical stimulation lead in a minimally invasive percutaneous manner to enable electrical stimulation of a human's spinal nerve tissue, comprising:

- inserting a needle into the epidural space;
- 5 inserting a guide wire through the needle until an end of the guide wire is positioned in the epidural space at a desired location relative to the spinal nerve tissue to be stimulated;
- verifying the position of the guide wire in the epidural space using fluoroscopy;
- removing the needle and leaving the guide wire substantially in position;
- advancing an introducer, comprising an outer sheath and an inner penetrator
- 10 removably housed within the outer sheath, the inner penetrator of the introducer comprising an inner channel configured to accommodate the guide wire and further comprising a hollow tapered tip configured to extend beyond the outer sheath, the outer sheath of the introducer having a width of at least approximately two times its height, along the guide wire until an end of the inner penetrator of the introducer is positioned in the epidural space at a desired
- 15 location with respect to the spinal nerve tissue to be stimulated, the outer sheath of the introducer forming a tract as the inner penetrator of the introducer advances along the guide wire;
- verifying the position of the introducer in the epidural space using fluoroscopy;
- removing the guide wire and the inner penetrator of the introducer and leaving the
- 20 outer sheath of the introducer substantially in position;
- inserting the electrical stimulation lead through the outer sheath of the introducer until the electrical stimulation lead is positioned in the epidural space proximate the spinal nerve tissue to be stimulated; and
- verifying positioning of the paddle style electrical stimulation lead in the epidural
- 25 space using fluoroscopy.

29. A method of implanting a system to enable electrical stimulation of a human's nerve tissue, comprising:

inserting a needle into tissue proximate nerve tissue to be stimulated;

5 inserting a guide wire through the needle until an end of the guide wire is positioned at a desired location relative to nerve tissue to be stimulated;

removing the needle and leaving the guide wire substantially in position;

10 advancing along a guide wire an introducer, comprising an outer sheath and an inner penetrator removably housed within the outer sheath, the inner penetrator of the introducer comprising an inner channel configured to accommodate the guide wire and further comprising a hollow tip extending beyond the outer sheath, until an end of the inner penetrator of the introducer is positioned at a desired location relative to nerve tissue to be stimulated, the outer sheath of the introducer forming an insertion tract as the inner penetrator of the introducer advances along the guide wire;

15 removing the guide wire and the inner penetrator of the introducer and leaving the outer sheath of the introducer substantially in position;

inserting an electrical stimulation lead through the outer sheath of the introducer until the electrical stimulation lead is positioned proximate the nerve tissue to be stimulated;

removing the outer sheath;

connecting the electrical stimulation lead to a generator;

20 creating a subcutaneous pocket for a generator; and

inserting the generator into the subcutaneous pocket.

30. A system for implanting an electrical stimulation lead to enable electrical stimulation of a human's spinal nerve tissue, comprising:

a needle;

a guide wire;

5 an introducer comprising an outer sheath and an inner penetrator;

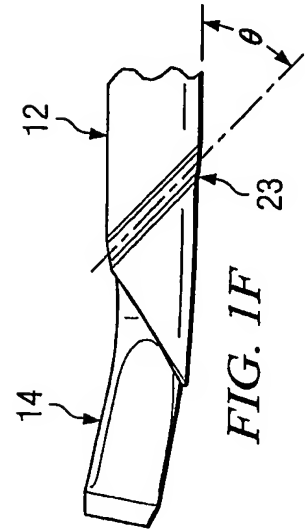
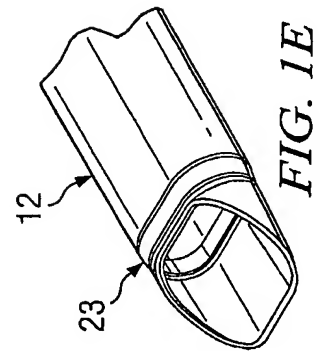
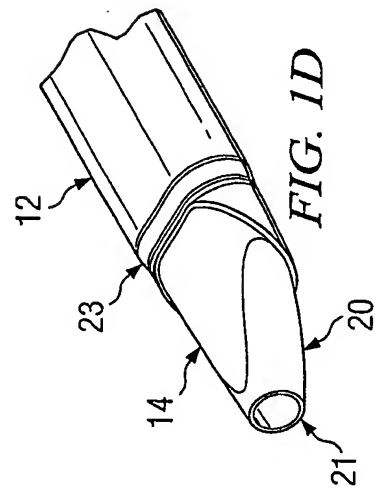
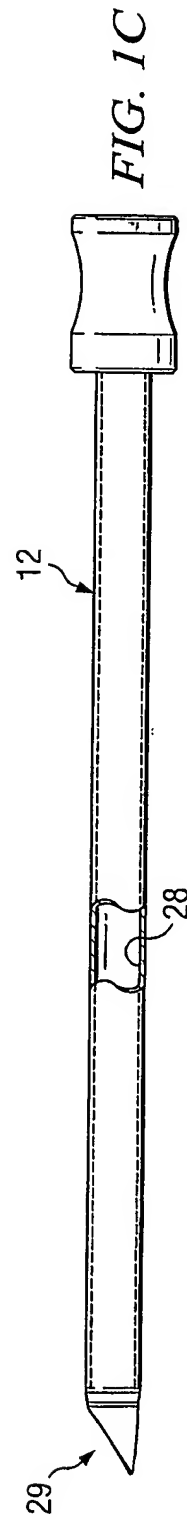
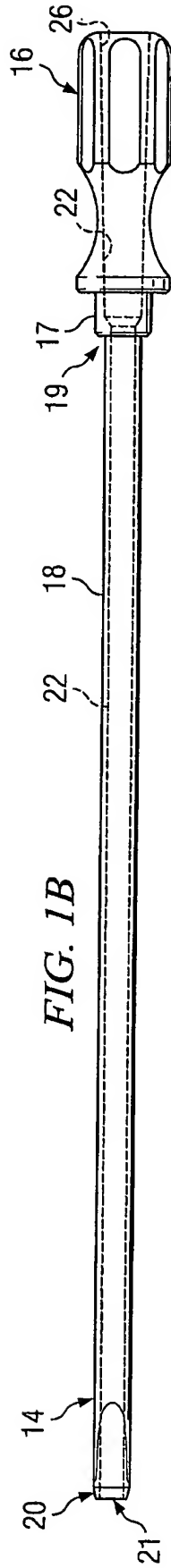
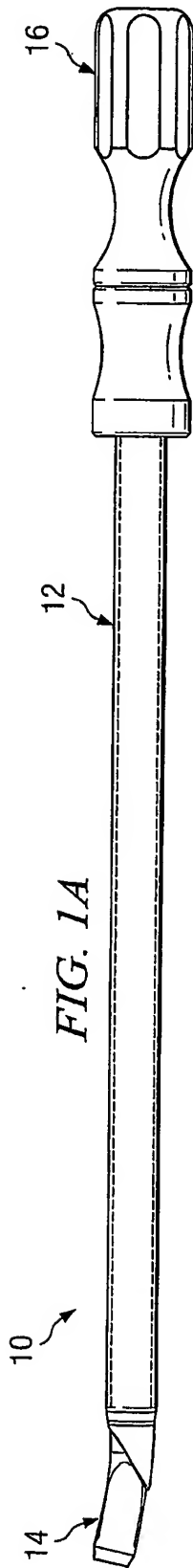
the outer sheath configured to accommodate insertion of the electrical stimulation lead through the outer sheath, the outer sheath operable to be inserted through the human's skin and into the human's epidural space;

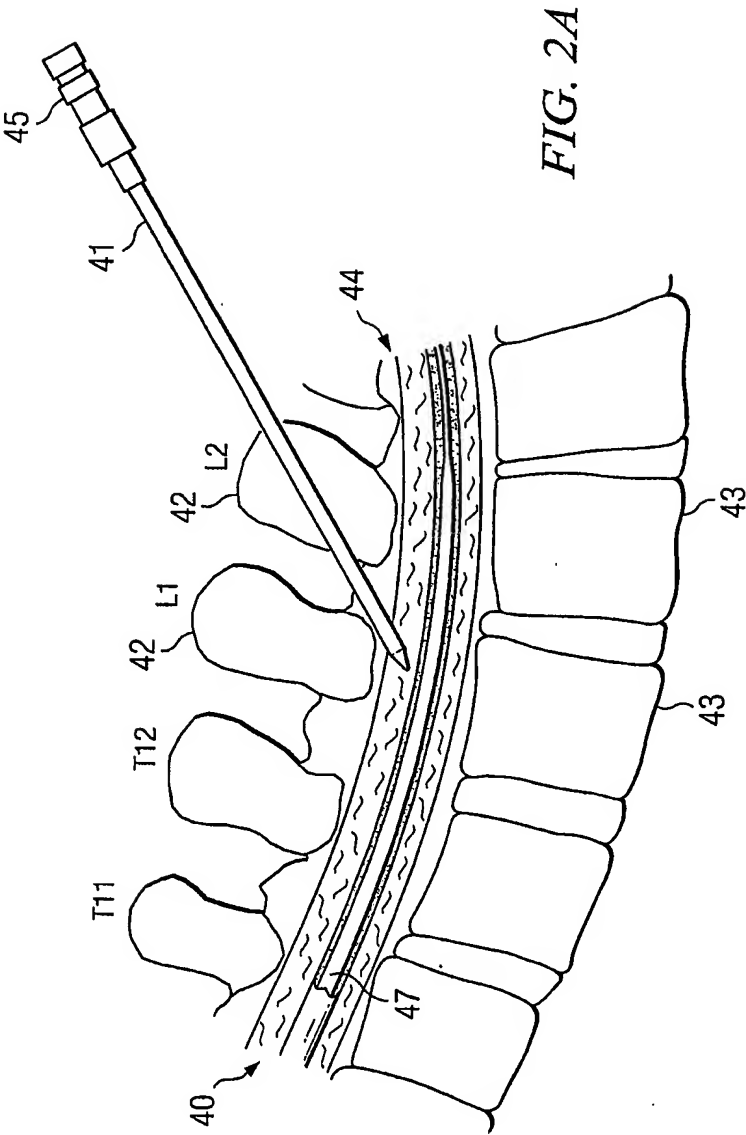
10 an inner penetrator removably housed within the outer sheath and comprising an inner channel configured to accommodate a guide wire;

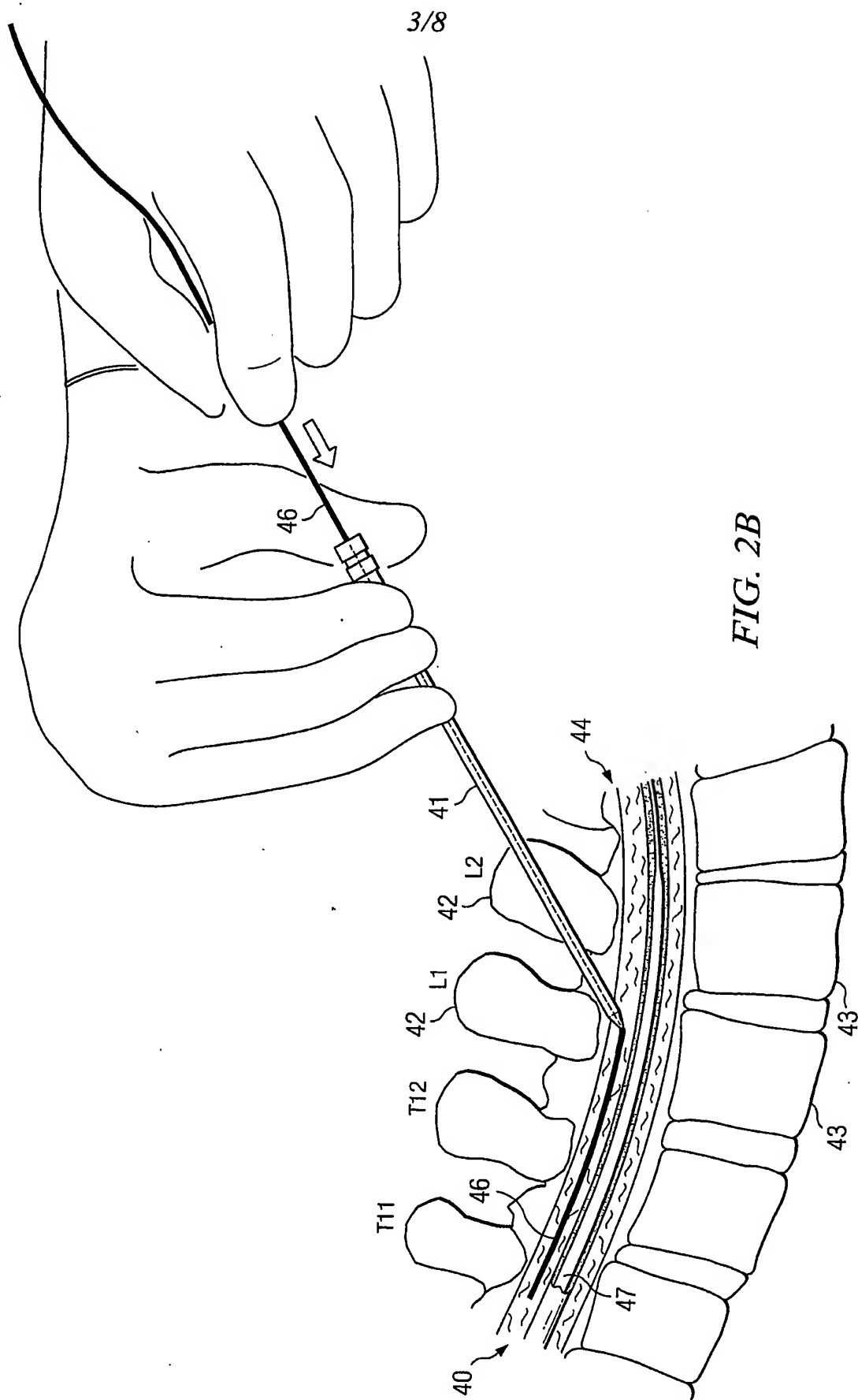
the inner penetrator configured to be advanced along the guide wire until an end of the inner penetrator is positioned in the epidural space at a desired location relative to spinal nerve tissue to be stimulated such that the outer sheath forms an insertion tract for the electrical stimulation lead as the inner penetrator advances along the guide wire, the inner
15 penetrator configured to be removed from the outer sheath leaving the outer sheath substantially in position in the epidural space for insertion of the electrical stimulation lead through the outer sheath into position proximate the spinal nerve tissue to be stimulated; and
an implantable generator to power the electrical stimulation lead.

31. A needle for introduction of a paddle style electrical stimulation lead near a
20 spinal column of a human, comprising in combination a body having a proximal end and a distal end, a lumen having a continuous oblong cross section defined by a solid outer wall, and a stylet having a handle at a proximal end and a solid body extending from the proximal end to a distal end and adapted to be inserted within the lumen, the improvement comprising:

25 a raised circumferential ridge configured to create resistance when the circumferential ridge contacts the human's ligamentum flavum.







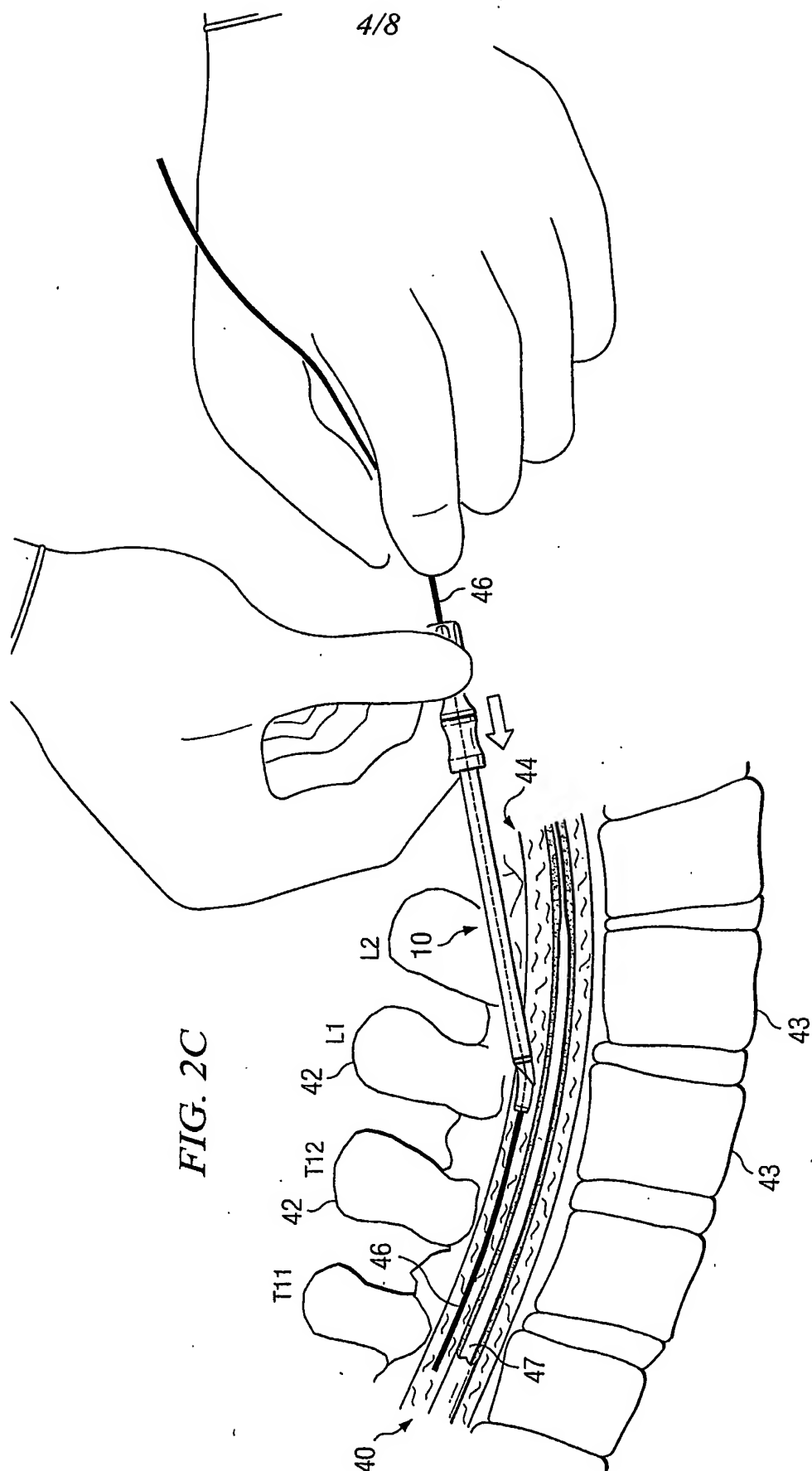
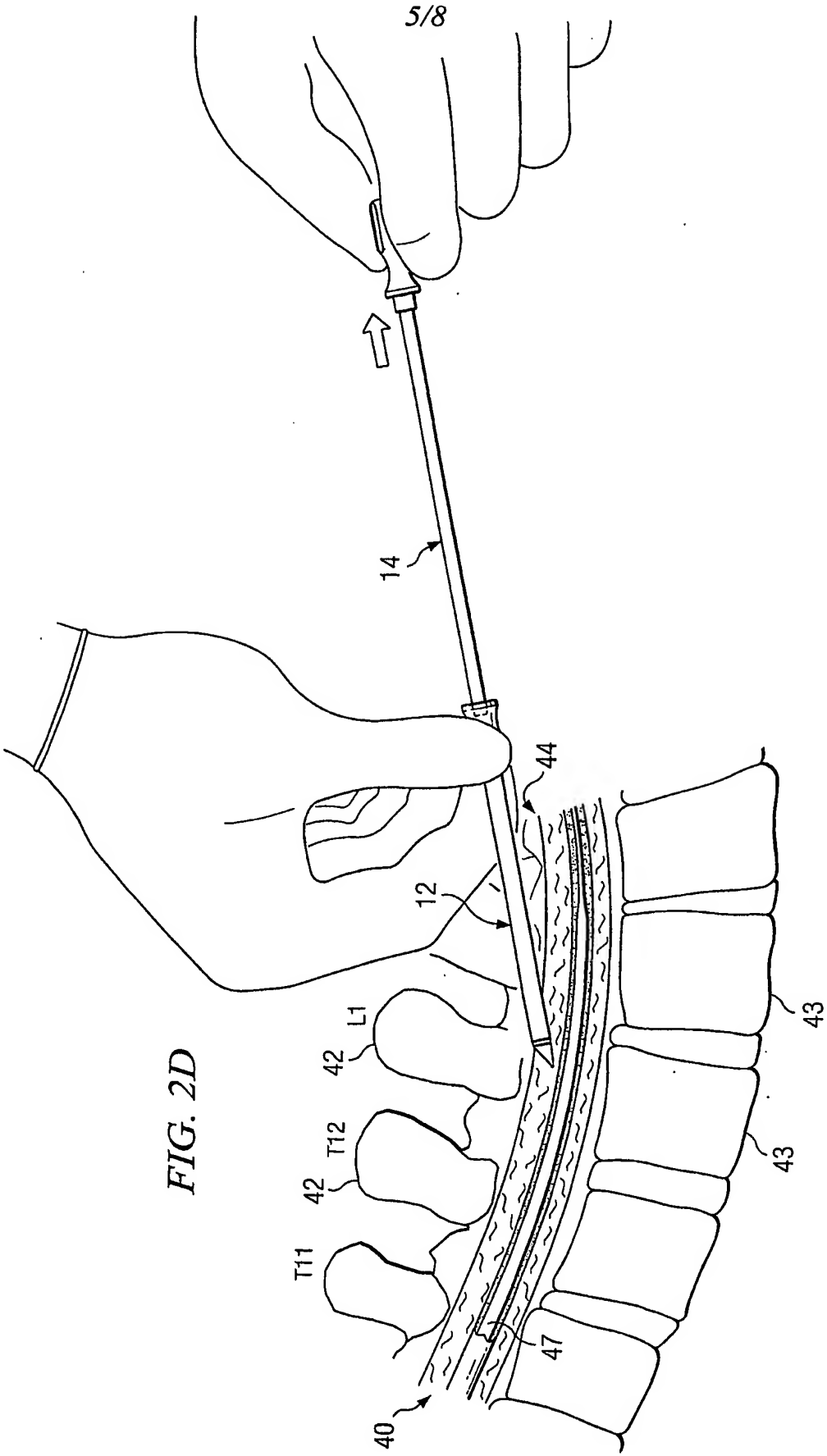


FIG. 2C



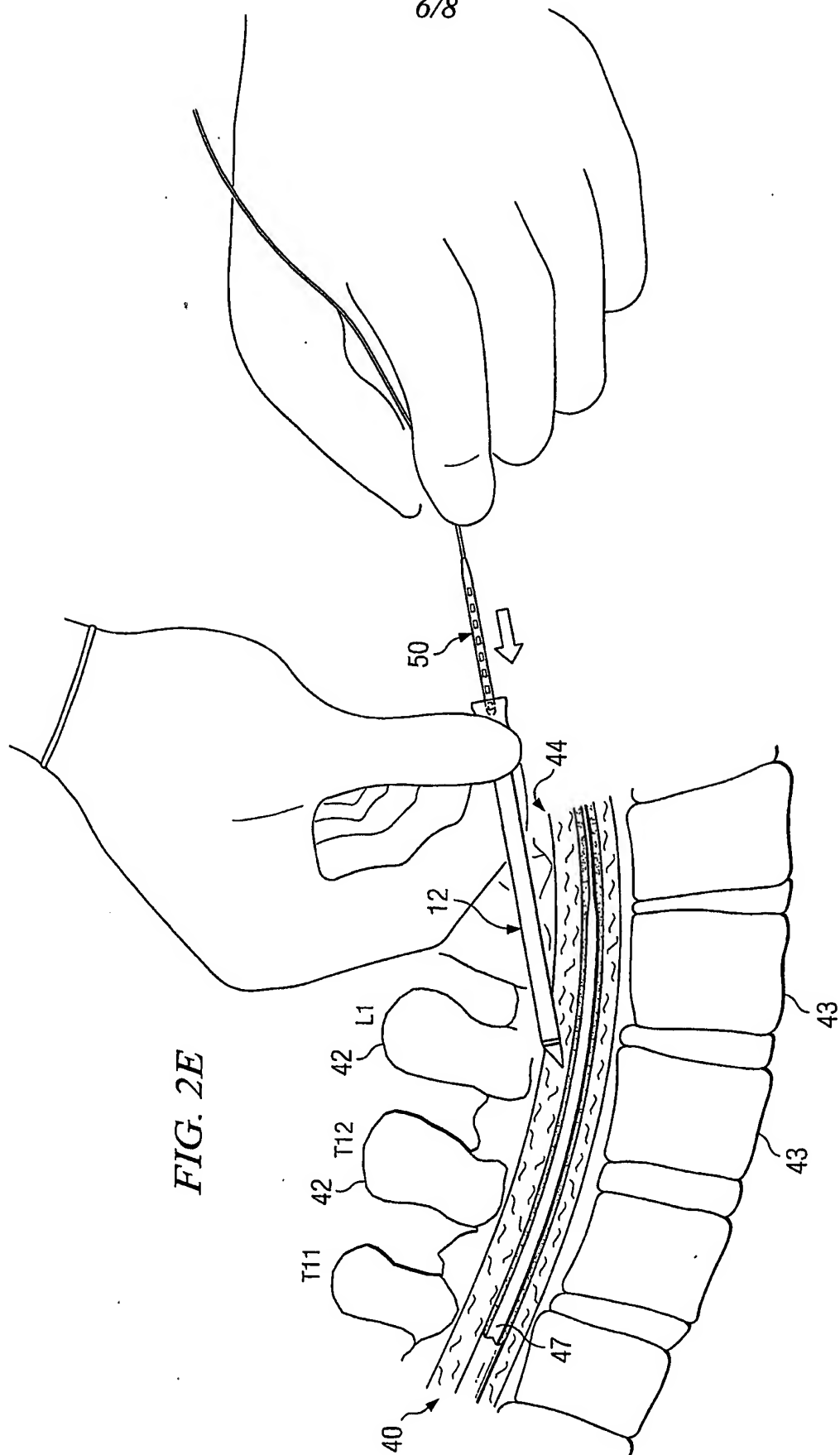


FIG. 2E

7/8

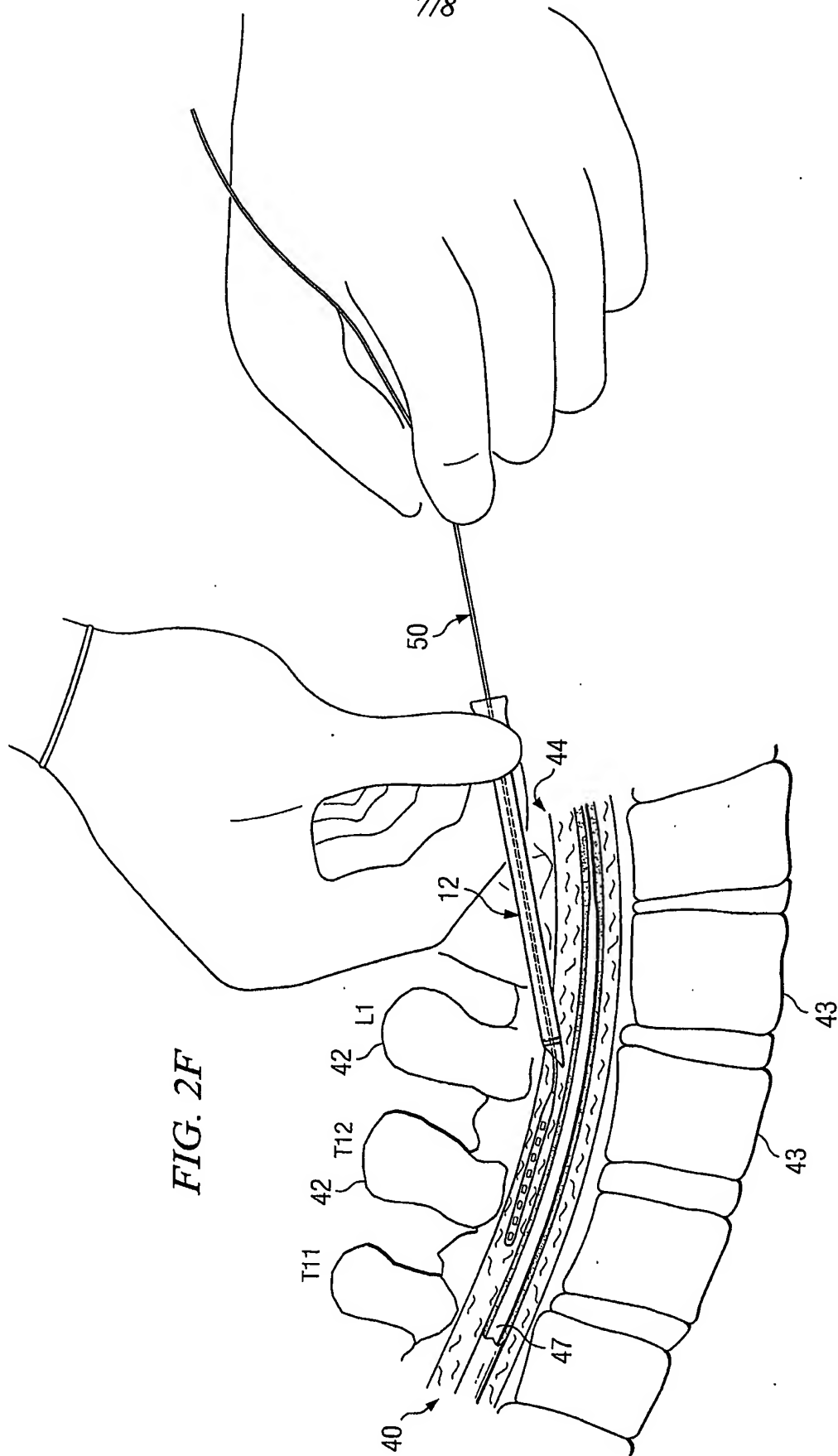
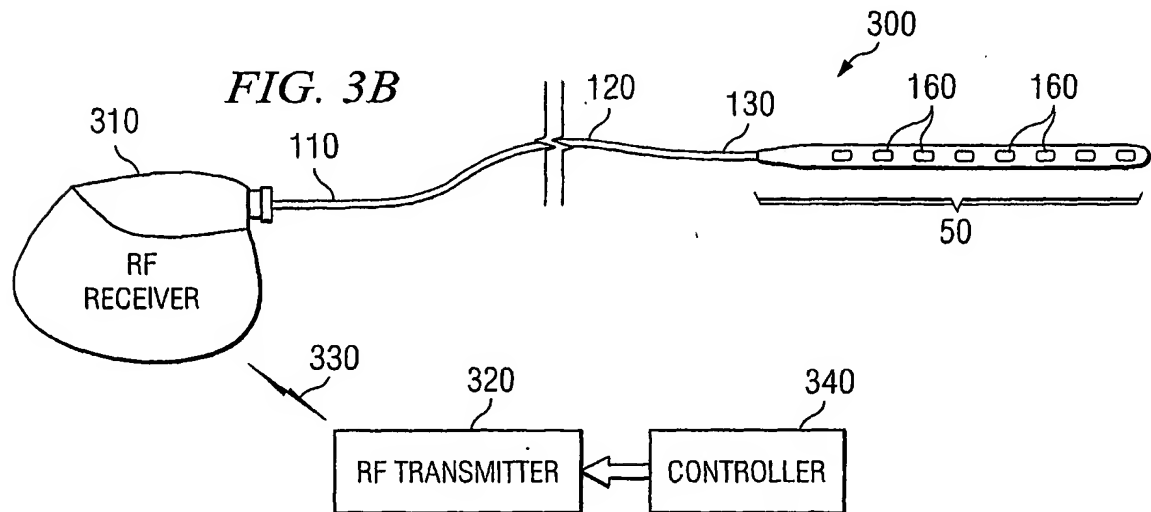
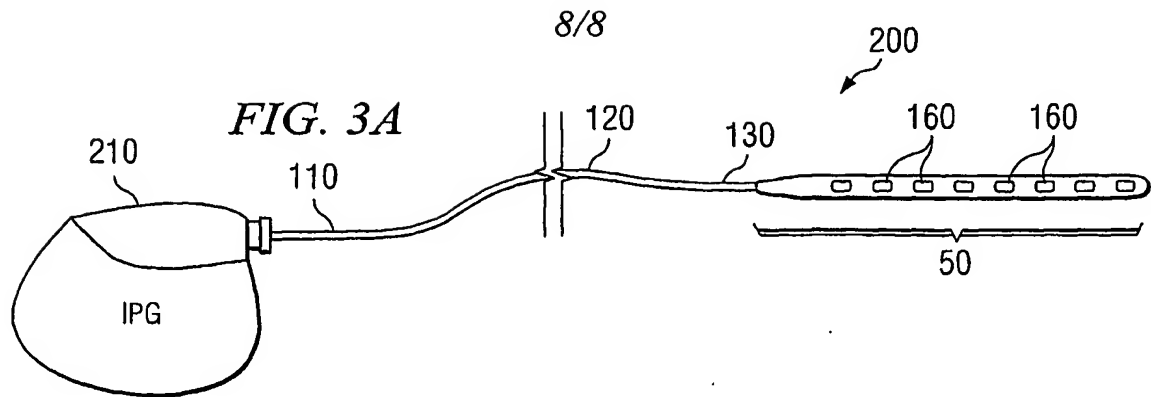
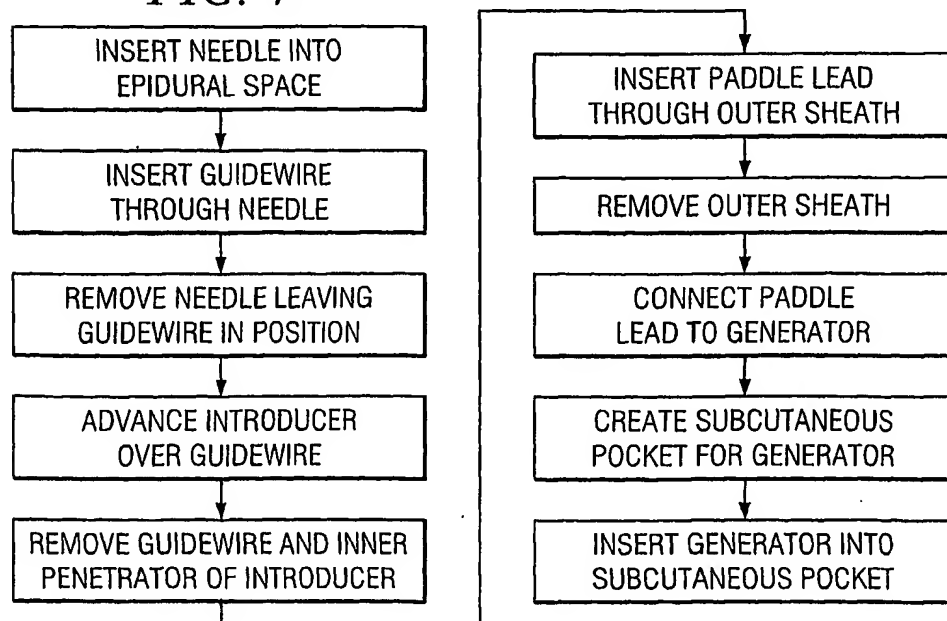


FIG. 2F

8/8

**FIG. 4**

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
24 February 2005 (24.02.2005)

PCT

(10) International Publication Number
WO 2005/016447 A3

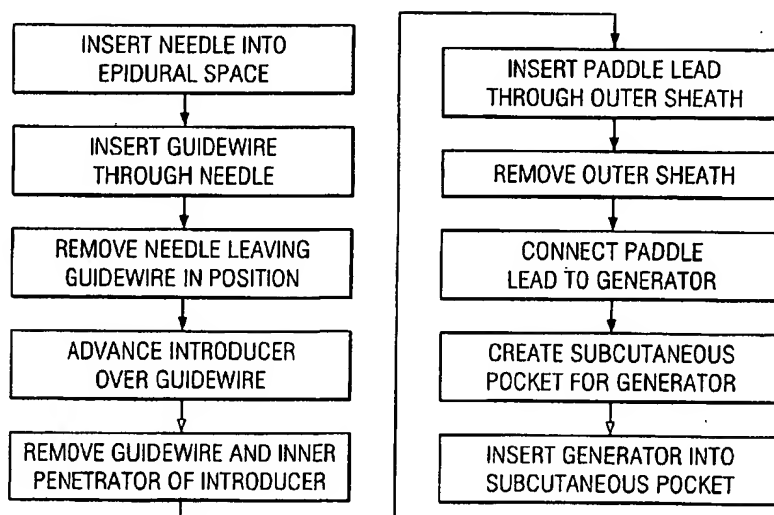
- (51) International Patent Classification⁷: **A61N 1/05**
- (21) International Application Number:
PCT/US2004/024552
- (22) International Filing Date: 28 July 2004 (28.07.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
10/637,342 8 August 2003 (08.08.2003) US
- (71) Applicant (for all designated States except US): **ADVANCED NEUROMODULATION SYSTEMS, INC.**
[US/US]; 6901 Preston Rd., Plano, TX 75024 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **DAGLOW, Terry**
[US/US]; 1005 Ashland Court, Allen, TX 75013 (US).
- (74) Agent: **KENNERLY, Christopher, W.**; Baker Botts, LLP,
2001 Ross Avenue, Dallas, TX 75201 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations

[Continued on next page]

(54) Title: APPARATUS AND METHOD FOR IMPLANTING AN ELECTRICAL STIMULATION SYSTEM AND A PADDLE STYLE ELECTRICAL STIMULATION LEAD



(57) Abstract: In one embodiment, an introducer is provided for implanting an electrical stimulation lead to enable electrical stimulation of nerve tissue. The introducer includes an outer sheath and an inner penetrator. The outer sheath is configured to accommodate insertion of the electrical stimulation lead through the outer sheath and may be inserted into a human body near the nerve tissue. The inner penetrator is removably housed within the outer sheath and includes an inner channel configured to accommodate a guide wire. The inner penetrator may be advanced along the guide wire to a desired location relative to the nerve tissue and removed from the outer sheath leaving the outer sheath substantially in position for insertion of the electrical stimulation lead through the outer sheath into position proximate the nerve tissue.

WO 2005/016447 A3



- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designation US*

(88) **Date of publication of the International search report:**
15 December 2005

Published:

- *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/024552

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/147485 A1 (SPINELLI MICHELE ET AL) 10 October 2002 (2002-10-10) abstract; figures 8a-c, 9a paragraph [0009] - paragraph [0015] paragraph [0070] - paragraph [0104]	1,2,5-7, 9,12,13, 16,30
Y		3,4,10, 11,14,15 8
A		
Y	WO 03/013650 A (DREES SCOTT F ; DAGLOW TERRY (US); ERICKSON JOHN H (US); ADVANCED NEUR) 20 February 2003 (2003-02-20) the whole document	3,4,10, 11,14,15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

15 December 2004

Date of mailing of the international search report

06.05.2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Wetzig, T

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/024552

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-29
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-16, 30

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16, 30

an introducer comprising an outer sheath, an inner penetrator housed within the outer sheath, the inner penetrator being configured to accommodate a guide wire

2. claim: 31

a needle in combination with a stylet, the needle comprising a circumferential ridge configured to create resistance when the circumferential ridge contacts the human's ligamentum flavum

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/024552

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002147485 A1	10-10-2002	NONE	
WO 03013650 A	20-02-2003	US 2003028654 A1 EP 1416999 A1 WO 03013650 A1	06-02-2003 12-05-2004 20-02-2003